

ASSEMBLY BILL

No. 830

**Introduced by Assembly Member Cook
(Principal coauthor: Assembly Member Krekorian)**

February 26, 2009

An act to amend Sections 13, 4025, 4053, and 4342 of the Business and Professions Code, to amend Sections 1367.21, 1370.4, 11014, 109920, 109985, 111656.4, and 150204 of the Health and Safety Code, to amend Sections 10123.195 and 10145.3 of the Insurance Code, to amend Section 47121 of the Public Resources Code, and to amend Sections 14105.43 and 14133.2 of the Welfare and Institutions Code, relating to drugs and devices.

LEGISLATIVE COUNSEL'S DIGEST

AB 830, as introduced, Cook. Drugs and devices.

Existing law references various drug compendia, including the United States Pharmacopoeia, in various health care provisions.

This bill would include within these references or any other similar drug compendium, as determined annually by the State Department of Health Care Services on the basis of factors, including, but not limited to, the breadth of listings, use of prespecified published criteria for weighing evidence, and inclusion on a list of compendia approved by the federal Centers for Medicare and Medicaid Services.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 13 of the Business and Professions Code is amended to read:

13. The term “materia medica” as used in this code or in any initiative act referred to in this code, means those substances listed in the official United States Pharmacopoeia, the official Homeopathic Pharmacopoeia of the United States, the official United States Dispensatory, New and Nonofficial Remedies, or the National Formulary, ~~or any supplement thereof, or any other similar drug compendium, as determined annually by the State Department of Health Care Services on the basis of factors, including, but not limited to, the breadth of listings, use of prespecified published criteria for weighing evidence, and inclusion on a list of compendia approved by the federal Centers for Medicare and Medicaid Services,~~ except substances covered by subdivision (a) of Section 4052 and Section 4057 ~~of this code~~.

SEC. 2. Section 4025 of the Business and Professions Code is amended to read:

4025. “Drug” means any of the following:

(a) Articles recognized in the official United States Pharmacopoeia, official National Formulary or official Homeopathic Pharmacopoeia of the United States, ~~or any supplement of any of them, or any other similar drug compendium, as determined annually by the State Department of Health Care Services on the basis of factors, including, but not limited to, the breadth of listings, use of prespecified published criteria for weighing evidence, and inclusion on a list of compendia approved by the federal Centers for Medicare and Medicaid Services.~~

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

(c) Articles (other than food) intended to affect the structure or any function of the body of humans or other animals.

(d) Articles intended for use as a component of any article specified in subdivision (a), (b), or (c).

SEC. 3. Section 4053 of the Business and Professions Code is amended to read:

4053. (a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal

1 drug retailer. The designated representative shall protect the public
2 health and safety in the handling, storage, and shipment of
3 dangerous drugs and dangerous devices in the wholesaler or
4 veterinary food-animal drug retailer.

5 (b) An individual may apply for a designated representative
6 license. In order to obtain and maintain that license, the individual
7 shall meet all of the following requirements:

8 (1) He or she shall be a high school graduate or possess a general
9 education development equivalent.

10 (2) He or she shall have a minimum of one year of paid work
11 experience, in the past three years, related to the distribution or
12 dispensing of dangerous drugs or dangerous devices or meet all
13 of the prerequisites to take the examination required for licensure
14 as a pharmacist by the board.

15 (3) He or she shall complete a training program approved by
16 the board that, at a minimum, addresses each of the following
17 subjects:

18 (A) Knowledge and understanding of California law and federal
19 law relating to the distribution of dangerous drugs and dangerous
20 devices.

21 (B) Knowledge and understanding of California law and federal
22 law relating to the distribution of controlled substances.

23 (C) Knowledge and understanding of quality control systems.

24 (D) Knowledge and understanding of the ~~United States~~
25 ~~Pharmacopoeia~~ standards relating to the safe storage and handling
26 of drugs *in the United States Pharmacopoeia or any other similar*
27 *drug compendium, as determined annually by the State Department*
28 *of Health Care Services on the basis of factors, including, but not*
29 *limited to, the breadth of listings, use of prespecified published*
30 *criteria for weighing evidence, and inclusion on a list of compendia*
31 *approved by the federal Centers for Medicare and Medicaid*
32 *Services.*

33 (E) Knowledge and understanding of prescription terminology,
34 abbreviations, dosages and format.

35 (4) The board may, by regulation, require training programs to
36 include additional material.

37 (5) The board may not issue a license as a designated
38 representative until the applicant provides proof of completion of
39 the required training to the board.

1 (c) The veterinary food-animal drug retailer or wholesaler shall
2 not operate without a pharmacist or a designated representative
3 on its premises.

4 (d) Only a pharmacist or a designated representative shall
5 prepare and affix the label to veterinary food-animal drugs.

6 (e) Section 4051 shall not apply to any laboratory licensed under
7 Section 351 of Title III of the Public Health Service Act (Public
8 Law 78-410).

9 SEC. 4. Section 4342 of the Business and Professions Code is
10 amended to read:

11 4342. (a) The board may institute any action or actions as may
12 be provided by law and that, in its discretion, are necessary, to
13 prevent the sale of pharmaceutical preparations and drugs that do
14 not conform to the standard and tests as to quality and strength,
15 provided in the ~~latest edition of the~~ United States Pharmacopoeia
16 ~~or, the National Formulary, or any other similar drug compendium,~~
17 *as determined annually by the State Department of Health Care*
18 *Services on the basis of factors, including, but not limited to, the*
19 *breadth of listings, use of prespecified published criteria for*
20 *weighing evidence, and inclusion on a list of compendia approved*
21 *by the federal Centers for Medicare and Medicaid Services* or that
22 violate any provision of the Sherman Food, Drug and Cosmetic
23 Law (Part 5 (commencing with Section 109875) of Division 104
24 of the Health and Safety Code).

25 (b) Any knowing or willful violation of any regulation adopted
26 pursuant to Section 4006 shall be subject to punishment in the
27 same manner as is provided in Sections 4336 and 4321.

28 SEC. 5. Section 1367.21 of the Health and Safety Code is
29 amended to read:

30 1367.21. (a) No health care service plan contract which covers
31 prescription drug benefits shall be issued, amended, delivered, or
32 renewed in this state if the plan limits or excludes coverage for a
33 drug on the basis that the drug is prescribed for a use that is
34 different from the use for which that drug has been approved for
35 marketing by the federal Food and Drug Administration (FDA),
36 provided that all of the following conditions have been met:

37 (1) The drug is approved by the FDA.

38 (2) (A) The drug is prescribed by a participating licensed health
39 care professional for the treatment of a life-threatening condition;

40 or

(B) The drug is prescribed by a participating licensed health care professional for the treatment of a chronic and seriously debilitating condition, the drug is medically necessary to treat that condition, and the drug is on the plan formulary. If the drug is not on the plan formulary, the participating subscriber's request shall be considered pursuant to the process required by Section 1367.24.

(3) The drug has been recognized for treatment of that condition by one of the following:

(A) The American Medical Association Drug Evaluations.

(B) The American Hospital Formulary Service Drug Information.

(C) The United States Pharmacopoeia Dispensing Information, Volume 1, "Drug Information for the Health Care Professional," *Professional" or any other similar drug compendium, as determined annually by the State Department of Health Care Services on the basis of factors, including, but not limited to, the breadth of listings, use of prespecified published criteria for weighing evidence, and inclusion on a list of compendia approved by the federal Centers for Medicare and Medicaid Services.*

(D) Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

(b) It shall be the responsibility of the participating prescriber to submit to the plan documentation supporting compliance with the requirements of subdivision (a), if requested by the plan.

(c) Any coverage required by this section shall also include medically necessary services associated with the administration of a drug, subject to the conditions of the contract.

(d) For purposes of this section, "life-threatening" means either or both of the following:

(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(e) For purposes of this section, "chronic and seriously debilitating" means diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.

1 (f) The provision of drugs and services when required by this
2 section shall not, in itself, give rise to liability on the part of the
3 plan.

4 (g) Nothing in this section shall be construed to prohibit the use
5 of a formulary, copayment, technology assessment panel, or similar
6 mechanism as a means for appropriately controlling the utilization
7 of a drug that is prescribed for a use that is different from the use
8 for which that drug has been approved for marketing by the FDA.

9 (h) If a plan denies coverage pursuant to this section on the basis
10 that its use is experimental or investigational, that decision is
11 subject to review under Section 1370.4.

12 (i) Health care service plan contracts for the delivery of
13 Medi-Cal services under the Waxman-Duffy Prepaid Health Plan
14 Act (Chapter 8 (commencing with Section 14200) of Part 3 of
15 Division 9 of the Welfare and Institutions Code) are exempt from
16 the requirements of this section.

17 SEC. 6. Section 1370.4 of the Health and Safety Code is
18 amended to read:

19 1370.4. (a) Every health care service plan shall provide an
20 external, independent review process to examine the plan's
21 coverage decisions regarding experimental or investigational
22 therapies for individual enrollees who meet all of the following
23 criteria:

24 (1) (A) The enrollee has a life-threatening or seriously
25 debilitating condition.

26 (B) For purposes of this section, "life-threatening" means either
27 or both of the following:

28 (i) Diseases or conditions where the likelihood of death is high
29 unless the course of the disease is interrupted.

30 (ii) Diseases or conditions with potentially fatal outcomes, where
31 the end point of clinical intervention is survival.

32 (C) For purposes of this section, "seriously debilitating" means
33 diseases or conditions that cause major irreversible morbidity.

34 (2) The enrollee's physician certifies that the enrollee has a
35 condition, as defined in paragraph (1), for which standard therapies
36 have not been effective in improving the condition of the enrollee,
37 for which standard therapies would not be medically appropriate
38 for the enrollee, or for which there is no more beneficial standard
39 therapy covered by the plan than the therapy proposed pursuant
40 to paragraph (3).

1 (3) Either (A) the enrollee's physician, who is under contract
2 with or employed by the plan, has recommended a drug, device,
3 procedure or other therapy that the physician certifies in writing
4 is likely to be more beneficial to the enrollee than any available
5 standard therapies, or (B) the enrollee, or the enrollee's physician
6 who is a licensed, board-certified or board-eligible physician
7 qualified to practice in the area of practice appropriate to treat the
8 enrollee's condition, has requested a therapy that, based on two
9 documents from the medical and scientific evidence, as defined
10 in subdivision (d), is likely to be more beneficial for the enrollee
11 than any available standard therapy. The physician certification
12 pursuant to this subdivision shall include a statement of the
13 evidence relied upon by the physician in certifying his or her
14 recommendation. Nothing in this subdivision shall be construed
15 to require the plan to pay for the services of a nonparticipating
16 physician provided pursuant to this subdivision, that are not
17 otherwise covered pursuant to the plan contract.

18 (4) The enrollee has been denied coverage by the plan for a
19 drug, device, procedure, or other therapy recommended or
20 requested pursuant to paragraph (3).

21 (5) The specific drug, device, procedure, or other therapy
22 recommended pursuant to paragraph (3) would be a covered
23 service, except for the plan's determination that the therapy is
24 experimental or investigational.

25 (b) The plan's decision to delay, deny, or modify experimental
26 or investigational therapies shall be subject to the independent
27 medical review process under Article 5.55 (commencing with
28 Section 1374.30) except that, in lieu of the information specified
29 in subdivision (b) of Section 1374.33, an independent medical
30 reviewer shall base his or her determination on relevant medical
31 and scientific evidence, including, but not limited to, the medical
32 and scientific evidence defined in subdivision (d).

33 (c) The independent medical review process shall also meet the
34 following criteria:

35 (1) The plan shall notify eligible enrollees in writing of the
36 opportunity to request the external independent review within five
37 business days of the decision to deny coverage.

38 (2) If the enrollee's physician determines that the proposed
39 therapy would be significantly less effective if not promptly
40 initiated, the analyses and recommendations of the experts on the

1 panel shall be rendered within seven days of the request for
2 expedited review. At the request of the expert, the deadline shall
3 be extended by up to three days for a delay in providing the
4 documents required. The timeframes specified in this paragraph
5 shall be in addition to any otherwise applicable timeframes
6 contained in subdivision (c) of Section 1374.33.

7 (3) Each expert's analysis and recommendation shall be in
8 written form and state the reasons the requested therapy is or is
9 not likely to be more beneficial for the enrollee than any available
10 standard therapy, and the reasons that the expert recommends that
11 the therapy should or should not be provided by the plan, citing
12 the enrollee's specific medical condition, the relevant documents
13 provided, and the relevant medical and scientific evidence,
14 including, but not limited to, the medical and scientific evidence
15 as defined in subdivision (d), to support the expert's
16 recommendation.

17 (4) Coverage for the services required under this section shall
18 be provided subject to the terms and conditions generally applicable
19 to other benefits under the plan contract.

20 (d) For the purposes of subdivision (b), "medical and scientific
21 evidence" means the following sources:

22 (1) Peer-reviewed scientific studies published in or accepted
23 for publication by medical journals that meet nationally recognized
24 requirements for scientific manuscripts and that submit most of
25 their published articles for review by experts who are not part of
26 the editorial staff.

27 (2) Peer-reviewed literature, biomedical compendia, and other
28 medical literature that meet the criteria of the National Institutes
29 of Health's National Library of Medicine for indexing in Index
30 Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS
31 data base Health Services Technology Assessment Research
32 (HSTAR).

33 (3) Medical journals recognized by the Secretary of Health and
34 Human Services, under Section 1861(t)(2) of the Social Security
35 Act.

36 (4) The following standard reference compendia: The American
37 Hospital Formulary Service-Drug Information, the American
38 Medical Association Drug Evaluation, the American Dental
39 Association Accepted Dental Therapeutics, ~~and~~ the United States
40 Pharmacopoeia-Drug Information, *or any other similar drug*

1 *compendium, as determined annually by the State Department of*
2 *Health Care Services on the basis of factors, including, but not*
3 *limited to, the breadth of listings, use of prespecified published*
4 *criteria for weighing evidence, and inclusion on a list of compendia*
5 *approved by the federal Centers for Medicare and Medicaid*
6 *Services.*

7 (5) Findings, studies, or research conducted by or under the
8 auspices of federal government agencies and nationally recognized
9 federal research institutes, including the Federal Agency for Health
10 Care Policy and Research, National Institutes of Health, National
11 Cancer Institute, National Academy of Sciences, Health Care
12 Financing Administration, Congressional Office of Technology
13 Assessment, and any national board recognized by the National
14 Institutes of Health for the purpose of evaluating the medical value
15 of health services.

16 (6) Peer-reviewed abstracts accepted for presentation at major
17 medical association meetings.

18 (e) The independent review process established by this section
19 shall be required on and after January 1, 2001.

20 SEC. 7. Section 11014 of the Health and Safety Code is
21 amended to read:

22 11014. "Drug" means (a) substances recognized as drugs in
23 the official United States Pharmacopoeia, official Homeopathic
24 Pharmacopoeia of the United States, ~~or~~ official National Formulary,
25 ~~or~~ any supplement to any of them; *or any other similar drug*
26 *compendium, as determined annually by the State Department of*
27 *Health Care Services on the basis of factors, including, but not*
28 *limited to, the breadth of listings, use of prespecified published*
29 *criteria for weighing evidence, and inclusion on a list of compendia*
30 *approved by the federal Centers for Medicare and Medicaid*
31 *Services;* (b) substances intended for use in the diagnosis, cure,
32 mitigation, treatment, or prevention of disease in man or animals;
33 (c) substances (other than food) intended to affect the structure or
34 any function of the body of man or animals; and (d) substances
35 intended for use as a component of any article specified in
36 subdivision (a), (b), or (c) of this section. It does not include
37 devices or their components, parts, or accessories.

38 SEC. 8. Section 109920 of the Health and Safety Code is
39 amended to read:

1 109920. “Device” means any instrument, apparatus, implement,
2 machine, contrivance, implant, in vitro reagent, or other similar
3 or related article, including any component, part, or accessory, that
4 is any of the following:

5 (a) Recognized in the official National Formulary ~~or~~, the United
6 States Pharmacopoeia, ~~or~~ any supplement to them, *or any other*
7 *similar drug compendium, as determined annually by the State*
8 *Department of Health Care Services on the basis of factors,*
9 *including, but not limited to, the breadth of listings, use of*
10 *prespecified published criteria for weighing evidence, and inclusion*
11 *on a list of compendia approved by the federal Centers for*
12 *Medicare and Medicaid Services.*

13 (b) Intended for use in the diagnosis of disease or other
14 condition, or in the cure, mitigation, treatment, or prevention of
15 disease in humans or any other animal.

16 (c) Intended to affect the structure or any function of the body
17 of humans or any other animal and that does not achieve any of
18 its principal intended purposes through chemical action within or
19 on the body of humans or other animals and that is not dependent
20 upon being metabolized for the achievement of any of its principal
21 intended purposes.

22 SEC. 9. Section 109985 of the Health and Safety Code is
23 amended to read:

24 109985. “Official compendium” means the latest edition of
25 the United States Pharmacopoeia, the latest edition of the
26 Homeopathic Pharmacopoeia of the United States, or the latest
27 edition of the National Formulary, ~~or~~ any supplement to any of
28 these, *or any other similar drug compendium, as determined*
29 *annually by the State Department of Health Care Services on the*
30 *basis of factors, including, but not limited to, the breadth of listings,*
31 *use of prespecified published criteria for weighing evidence, and*
32 *inclusion on a list of compendia approved by the federal Centers*
33 *for Medicare and Medicaid Services.*

34 SEC. 10. Section 111656.4 of the Health and Safety Code is
35 amended to read:

36 111656.4. Section 4051 of the Business and Professions Code
37 shall not prohibit a home medical device retail facility from selling
38 or dispensing prescription devices if the department finds that
39 sufficient qualified supervision is employed by the home medical
40 device retail facility to adequately safeguard and protect the public

1 health. Each person applying to the department for this exemption
2 shall meet the following requirements to obtain and maintain the
3 exemption:

4 (a) A licensed pharmacist or an exemptee who meets the
5 requirements set forth in paragraphs (1) to (5), inclusive, and whose
6 license of exemption is currently valid, shall be in charge of the
7 home medical device retail facility.

8 (1) He or she shall be a high school graduate or possess a general
9 education development equivalent.

10 (2) He or she shall have a minimum of one year of paid work
11 experience related to the distribution or dispensing of dangerous
12 drugs or dangerous devices.

13 (3) He or she shall complete a training program that addresses
14 each of the following subjects that are applicable to his or her
15 duties:

16 (A) Knowledge and understanding of state and federal laws
17 relating to the distribution of dangerous drugs and dangerous
18 devices.

19 (B) Knowledge and understanding of state and federal laws
20 relating the distribution of controlled substances.

21 (C) Knowledge and understanding of quality control systems.

22 (D) Knowledge and understanding of the ~~United States~~
23 ~~Pharmacopoeia~~ standards relating to the safe storage and handling
24 of drugs *in the United States Pharmacopoeia or any other similar*
25 *drug compendium, as determined annually by the State Department*
26 *of Health Care Services on the basis of factors, including, but not*
27 *limited to, the breadth of listings, use of prespecified published*
28 *criteria for weighing evidence, and inclusion on a list of compendia*
29 *approved by the federal Centers for Medicare and Medicaid*
30 *Services.*

31 (E) Knowledge and understanding relating to the safe storage
32 and handling of home medical devices.

33 (F) Knowledge and understanding of prescription terminology,
34 abbreviations, and format.

35 (4) The department may, by regulation, require training
36 programs that include additional material.

37 (5) The department shall not issue an exemptee a license until
38 the applicant provides proof of completion of the required training
39 that the department determines is adequate to fulfill these
40 requirements.

(b) The licensed pharmacist or exemptee shall be on the premises at all times that prescription devices are available for sale or fitting unless the prescription devices are stored separately from other merchandise and are under the exclusive control of the licensed pharmacist or exemptee. A licensed pharmacist or an exemptee need not be present in the warehouse facility of a home medical device retail facility unless the department establishes that requirement by regulation based upon the need to protect the public.

(c) The department may require an exemptee to complete a designated number of hours of coursework in department-approved courses of home health education in the disposition of any disciplinary action taken against the exemptee.

(d) Each premises maintained by a home medical device retail facility shall have a license issued by the department and shall have a licensed pharmacist or exemptee on the premises if prescription devices are furnished, sold, or dispensed.

(e) A home medical device retail facility may establish locked storage (a lock box or locked area) for emergency or after working hours furnishing of prescription devices. Locked storage may be installed or placed in a service vehicle of the home medical device retail facility for emergency or after hours service to patients having prescriptions for prescription devices.

(f) The department may by regulation authorize a licensed pharmacist or exemptee to direct an employee of the home medical device retail facility who operates the service vehicle equipped with locked storage described in subdivision (e) to deliver a prescription device from the locked storage to patients having prescriptions for prescription devices. These regulations shall establish inventory requirements for the locked storage by a licensed pharmacist or exemptee to take place shortly after a prescription device has been delivered from the locked storage to a patient.

SEC. 11. Section 150204 of the Health and Safety Code is amended to read:

150204. (a) A county may establish, by ordinance, a repository and distribution program for purposes of this division. Only pharmacies that are county-owned or that contract with the county pursuant to this division may participate in this program to dispense medication donated to the drug repository and distribution program.

1 (b) A county that elects to establish a repository and distribution
2 program pursuant to this division shall establish procedures for,
3 at a minimum, all of the following:

4 (1) Establishing eligibility for medically indigent patients who
5 may participate in the program.

6 (2) Ensuring that patients eligible for the program shall not be
7 charged for any medications provided under the program.

8 (3) Developing a formulary of medications appropriate for the
9 repository and distribution program.

10 (4) Ensuring proper safety and management of any medications
11 collected by and maintained under the authority of a county-owned
12 or county-contracted, licensed pharmacy.

13 (5) Ensuring the privacy of individuals for whom the medication
14 was originally prescribed.

15 (c) Any medication donated to the repository and distribution
16 program shall comply with the requirements specified in this
17 division. Medication donated to the repository and distribution
18 program shall meet all of the following criteria:

19 (1) The medication shall not be a controlled substance.

20 (2) The medication shall not have been adulterated, misbranded,
21 or stored under conditions contrary to standards set by the United
22 States Pharmacopoeia (USP) *or in any other similar drug*
23 *compendium, as determined annually by the State Department of*
24 *Health Care Services on the basis of factors, including, but not*
25 *limited to, the breadth of listings, use of prespecified published*
26 *criteria for weighing evidence, and inclusion on a list of compendia*
27 *approved by the federal Centers for Medicare and Medicaid*
28 *Services or the product manufacturer.*

29 (3) The medication shall not have been in the possession of a
30 patient or any individual member of the public, and in the case of
31 medications donated by a skilled nursing facility, shall have been
32 under the control of staff of the skilled nursing facility.

33 (d) Only medication that is donated in unopened, tamper-evident
34 packaging or modified unit dose containers that meet—USP
35 standards *in the USP or in any other similar drug compendium,*
36 *as determined annually by the State Department of Health Care*
37 *Services on the basis of factors, including, but not limited to, the*
38 *breadth of listings, use of prespecified published criteria for*
39 *weighing evidence, and inclusion on a list of compendia approved*
40 *by the federal Centers for Medicare and Medicaid Services* is

1 eligible for donation to the repository and distribution program,
2 provided lot numbers and expiration dates are affixed. Medication
3 donated in opened containers shall not be dispensed by the
4 repository and distribution program.

5 (e) A pharmacist shall use his or her professional judgment in
6 determining whether donated medication meets the standards of
7 this division before accepting or dispensing any medication under
8 the repository and distribution program.

9 (f) A pharmacist shall adhere to standard pharmacy practices,
10 as required by state and federal law, when dispensing all
11 medications.

12 (g) Medication that is donated to the repository and distribution
13 program shall be handled in any of the following ways:

14 (1) Dispensed to an eligible patient.

15 (2) Destroyed.

16 (3) Returned to a reverse distributor.

17 (h) Medication that is donated to the repository and distribution
18 program that does not meet the requirements of this division shall
19 not be distributed under this program and shall be either destroyed
20 or returned to a reverse distributor. This medication shall not be
21 sold, dispensed, or otherwise transferred to any other entity.

22 (i) Medication donated to the repository and distribution program
23 shall be maintained in the donated packaging units until dispensed
24 to an eligible patient under this program, who presents a valid
25 prescription. When dispensed to an eligible patient under this
26 program, the medication shall be in a new and properly labeled
27 container, specific to the eligible patient and ensuring the privacy
28 of the individuals for whom the medication was initially dispensed.
29 Expired medication shall not be dispensed.

30 (j) Medication donated to the repository and distribution program
31 shall be segregated from the pharmacy's other drug stock by
32 physical means, for purposes including, but not limited to,
33 inventory, accounting, and inspection.

34 (k) The pharmacy shall keep complete records of the acquisition
35 and disposition of medication donated to and dispensed under the
36 repository and distribution program. These records shall be kept
37 separate from the pharmacy's other acquisition and disposition
38 records and shall conform to the Pharmacy Law (Chapter 9
39 (commencing with Section 4000) of Division 2 of the Business
40 and Professions Code), including being readily retrievable.

1 (l) Local and county protocols established pursuant to this
2 division shall conform to the Pharmacy Law regarding packaging,
3 transporting, storing, and dispensing all medications.

4 (m) County protocols established for packaging, transporting,
5 storing, and dispensing medications that require refrigeration,
6 including, but not limited to, any biological product as defined in
7 Section 351 of the Public Health and Service Act (42 U.S.C. Sec.
8 262), an intravenously injected drug, or an infused drug, include
9 specific procedures to ensure that these medications are packaged,
10 transported, stored, and dispensed at their appropriate temperatures
11 and in accordance with—USP *DrugPoint* standards and the
12 Pharmacy Law.

13 (n) Notwithstanding any other provision of law, a participating
14 county-owned or county-contracted pharmacy shall follow the
15 same procedural drug pedigree requirements for donated drugs as
16 it would follow for drugs purchased from a wholesaler or directly
17 from a drug manufacturer.

18 SEC. 12. Section 10123.195 of the Insurance Code is amended
19 to read:

20 10123.195. (a) No group or individual disability insurance
21 policy issued, delivered, or renewed in this state or certificate of
22 group disability insurance issued, delivered, or renewed in this
23 state pursuant to a master group policy issued, delivered, or
24 renewed in another state that, as a provision of hospital, medical,
25 or surgical services, directly or indirectly covers prescription drugs
26 shall limit or exclude coverage for a drug on the basis that the drug
27 is prescribed for a use that is different from the use for which that
28 drug has been approved for marketing by the federal Food and
29 Drug Administration (FDA), provided that all of the following
30 conditions have been met:

31 (1) The drug is approved by the FDA.

32 (2) (A) The drug is prescribed by a contracting licensed health
33 care professional for the treatment of a life-threatening condition;
34 or

35 (B) The drug is prescribed by a contracting licensed health care
36 professional for the treatment of a chronic and seriously debilitating
37 condition, the drug is medically necessary to treat that condition,
38 and the drug is on the insurer's formulary, if any.

39 (3) The drug has been recognized for treatment of that condition
40 by one of the following:

1 (A) The American Medical Association Drug Evaluations.

2 (B) The American Hospital Formulary Service Drug
3 Information.

4 (C) The United States Pharmacopoeia Dispensing Information,
5 Volume 1, “Drug Information for the Health Care Professional.”

6 *Professional” or any other similar drug compendium, as*
7 *determined annually by the State Department of Health Care*
8 *Services on the basis of factors, including, but not limited to, the*
9 *breadth of listings, use of prespecified published criteria for*
10 *weighing evidence, and inclusion on a list of compendia approved*
11 *by the federal Centers for Medicare and Medicaid Services.*

12 (D) Two articles from major peer reviewed medical journals
13 that present data supporting the proposed off-label use or uses as
14 generally safe and effective unless there is clear and convincing
15 contradictory evidence presented in a major peer reviewed medical
16 journal.

17 (b) It shall be the responsibility of the contracting prescriber to
18 submit to the insurer documentation supporting compliance with
19 the requirements of subdivision (a), if requested by the insurer.

20 (c) Any coverage required by this section shall also include
21 medically necessary services associated with the administration
22 of a drug subject to the conditions of the contract.

23 (d) For purposes of this section, “life-threatening” means either
24 or both of the following:

25 (1) Diseases or conditions where the likelihood of death is high
26 unless the course of the disease is interrupted.

27 (2) Diseases or conditions with potentially fatal outcomes, where
28 the end point of clinical intervention is survival.

29 (e) For purposes of this section, “chronic and seriously
30 debilitating” means diseases or conditions that require ongoing
31 treatment to maintain remission or prevent deterioration and cause
32 significant long-term morbidity.

33 (f) The provision of drugs and services when required by this
34 section shall not, in itself, give rise to liability on the part of the
35 insurer.

36 (g) This section shall not apply to a policy of disability insurance
37 that covers hospital, medical, or surgical expenses which is issued
38 outside of California to an employer whose principal place of
39 business is located outside of California.

1 (h) Nothing in this section shall be construed to prohibit the use
2 of a formulary, copayment, technology assessment panel, or similar
3 mechanism as a means for appropriately controlling the utilization
4 of a drug that is prescribed for a use that is different from the use
5 for which that drug has been approved for marketing by the FDA.

6 (i) If an insurer denies coverage pursuant to this section on the
7 basis that its use is experimental or investigational, that decision
8 is subject to review under the Independent Medical Review System
9 of Article 3.5 (commencing with Section 10169).

10 (j) This section is not applicable to vision-only, dental-only,
11 Medicare or Champus supplement, disability income, long-term
12 care, accident-only, specified disease or hospital confinement
13 indemnity insurance.

14 SEC. 13. Section 10145.3 of the Insurance Code is amended
15 to read:

16 10145.3. (a) Every disability insurer that covers hospital,
17 medical, or surgical benefits shall provide an external, independent
18 review process to examine the insurer's coverage decisions
19 regarding experimental or investigational therapies for individual
20 insureds who meet all of the following criteria:

21 (1) (A) The insured has a life-threatening or seriously
22 debilitating condition.

23 (B) For purposes of this section, "life-threatening" means either
24 or both of the following:

25 (i) Diseases or conditions where the likelihood of death is high
26 unless the course of the disease is interrupted.

27 (ii) Diseases or conditions with potentially fatal outcomes, where
28 the end point of clinical intervention is survival.

29 (C) For purposes of this section, "seriously debilitating" means
30 diseases or conditions that cause major irreversible morbidity.

31 (2) The insured's physician certifies that the insured has a
32 condition, as defined in paragraph (1), for which standard therapies
33 have not been effective in improving the condition of the insured,
34 for which standard therapies would not be medically appropriate
35 for the insured, or for which there is no more beneficial standard
36 therapy covered by the insurer than the therapy proposed pursuant
37 to paragraph (3).

38 (3) Either (A) the insured's contracting physician has
39 recommended a drug, device, procedure, or other therapy that the
40 physician certifies in writing is likely to be more beneficial to the

1 insured than any available standard therapies, or (B) the insured,
2 or the insured's physician who is a licensed, board-certified or
3 board-eligible physician qualified to practice in the area of practice
4 appropriate to treat the insured's condition, has requested a therapy
5 that, based on two documents from the medical and scientific
6 evidence, as defined in subdivision (d), is likely to be more
7 beneficial for the insured than any available standard therapy. The
8 physician certification pursuant to this subdivision shall include a
9 statement of the evidence relied upon by the physician in certifying
10 his or her recommendation. Nothing in this subdivision shall be
11 construed to require the insurer to pay for the services of a
12 noncontracting physician, provided pursuant to this subdivision,
13 that are not otherwise covered pursuant to the contract.

14 (4) The insured has been denied coverage by the insurer for a
15 drug, device, procedure, or other therapy recommended or
16 requested pursuant to paragraph (3), unless coverage for the
17 specific therapy has been excluded by the insurer's contract.

18 (5) The specific drug, device, procedure, or other therapy
19 recommended pursuant to paragraph (3) would be a covered service
20 except for the insurer's determination that the therapy is
21 experimental or under investigation.

22 (b) The insurer's decision to deny, delay, or modify experimental
23 or investigational therapies shall be subject to the independent
24 medical review process established under Article 3.5 (commencing
25 with Section 10169) of Chapter 1 of Part 2 of Division 2, except
26 that in lieu of the information specified in subdivision (b) of
27 Section 10169.3, an independent medical reviewer shall base his
28 or her determination on relevant medical and scientific evidence,
29 including, but not limited to, the medical and scientific evidence
30 defined in subdivision (d).

31 (c) The independent medical review process shall also meet the
32 following criteria:

33 (1) The insurer shall notify eligible insureds in writing of the
34 opportunity to request the external independent review within five
35 business days of the decision to deny coverage.

36 (2) If the insured's physician determines that the proposed
37 therapy would be significantly less effective if not promptly
38 initiated, the analyses and recommendations of the experts on the
39 panel shall be rendered within seven days of the request for
40 expedited review. At the request of the expert, the deadline shall

1 be extended by up to three days for a delay in providing the
2 documents required. The timeframes specified in this paragraph
3 shall be in addition to any otherwise applicable timeframes
4 contained in subdivision (c) of Section 10169.3.

5 (3) Each expert's analysis and recommendation shall be in
6 written form and state the reasons the requested therapy is or is
7 not likely to be more beneficial for the insured than any available
8 standard therapy, and the reasons that the expert recommends that
9 the therapy should or should not be covered by the insurer, citing
10 the insured's specific medical condition, the relevant documents,
11 and the relevant medical and scientific evidence, including, but
12 not limited to, the medical and scientific evidence as defined in
13 subdivision (d), to support the expert's recommendation.

14 (4) Coverage for the services required under this section shall
15 be provided subject to the terms and conditions generally applicable
16 to other benefits under the contract.

17 (d) For the purposes of subdivision (b), "medical and scientific
18 evidence" means the following sources:

19 (1) Peer-reviewed scientific studies published in or accepted
20 for publication by medical journals that meet nationally recognized
21 requirements for scientific manuscripts and that submit most of
22 their published articles for review by experts who are not part of
23 the editorial staff.

24 (2) Peer-reviewed literature, biomedical compendia and other
25 medical literature that meet the criteria of the National Institutes
26 of Health's National Library of Medicine for indexing in Index
27 Medicus, Excerpta Medicus (EMBASE), Medline and MEDLARS
28 data base Health Services Technology Assessment Research
29 (HSTAR).

30 (3) Medical journals recognized by the Secretary of Health and
31 Human Services, under Section 1861(t)(2) of the Social Security
32 Act.

33 (4) The following standard reference compendia: The American
34 Hospital Formulary Service-Drug Information, the American
35 Medical Association Drug Evaluation, the American Dental
36 Association Accepted Dental Therapeutics~~and The~~, *the United*
37 *States Pharmacopoeia-Drug Information, or any other similar drug*
38 *compendium, as determined annually by the State Department of*
39 *Health Care Services on the basis of factors, including, but not*
40 *limited to, the breadth of listings, use of prespecified published*

1 *criteria for weighing evidence, and inclusion on a list of compendia*
2 *approved by the federal Centers for Medicare and Medicaid*
3 *Services.*

4 (5) Findings, studies, or research conducted by or under the
5 auspices of federal government agencies and nationally recognized
6 federal research institutes, including the Federal Agency for Health
7 Care Policy and Research, National Institutes of Health, National
8 Cancer Institute, National Academy of Sciences, Health Care
9 Financing Administration, Congressional Office of Technology
10 Assessment, and any national board recognized by the National
11 Institutes of Health for the purpose of evaluating the medical value
12 of health services.

13 (6) Peer-reviewed abstracts accepted for presentation at major
14 medical association meetings.

15 (e) The independent review process established by this section
16 shall be required on and after January 1, 2001.

17 SEC. 14. Section 47121 of the Public Resources Code is
18 amended to read:

19 47121. For the purposes of this article, the following terms
20 have the following meanings, unless the context clearly requires
21 otherwise:

22 (a) “Consumer” means an individual purchaser or owner of a
23 drug. “Consumer” does not include a business, corporation, limited
24 partnership, or an entity involved in a wholesale transaction
25 between a distributor and retailer.

26 (b) “Drug” means any of the following:

27 (1) Articles recognized in the official United States
28 Pharmacopoeia, the official National Formulary, the official
29 Homeopathic Pharmacopoeia of the United States, ~~or~~ any
30 supplement of the formulary or those pharmacopoeias, *or any other*
31 *similar drug compendium, as determined annually by the State*
32 *Department of Health Care Services on the basis of factors,*
33 *including, but not limited to, the breadth of listings, use of*
34 *prespecified published criteria for weighing evidence, and inclusion*
35 *on a list of compendia approved by the federal Centers for*
36 *Medicare and Medicaid Services.*

37 (2) Articles intended for use in the diagnosis, cure, mitigation,
38 treatment, or prevention of disease in humans or other animals.

39 (3) Articles, excluding food, intended to affect the structure or
40 function of the body of humans or other animals.

1 (4) Articles intended for use as a component of an article
2 specified in paragraph (1), (2), or (3).

3 (c) "Participant" means any entity which the board deems
4 appropriate for implementing and evaluating a model program and
5 which chooses to participate, including, but not limited to,
6 governmental entities, pharmacies, veterinarians, clinics, and other
7 medical settings.

8 (d) "Sale" includes, but is not limited to, transactions conducted
9 through sales outlets, catalogs, or the Internet, or any other similar
10 electronic means, but does not include a sale that is a wholesale
11 transaction with a distributor or retailer.

12 SEC. 15. Section 14105.43 of the Welfare and Institutions
13 Code is amended to read:

14 14105.43. (a) (1) Notwithstanding other provisions of this
15 chapter, any drug which is approved by the federal Food and Drug
16 Administration for use in the treatment of acquired-~~immune~~
17 ~~deficiency~~ immunodeficiency syndrome (AIDS) or an AIDS-related
18 condition shall be deemed to be approved for addition to the
19 Medi-Cal list of contract drugs only for the purpose of treating
20 AIDS or an AIDS-related condition, for the period prior to the
21 completion of the procedures established pursuant to Section
22 14105.33.

23 (2) (A) In addition to any drug that is deemed to be approved
24 pursuant to paragraph (1), any drug that meets any of the following
25 criteria shall be a Medi-Cal benefit, subject to utilization controls:

26 (i) Any vaccine to protect against human immunodeficiency
27 virus (HIV) infection.

28 (ii) Any antiviral agent, immune modulator, or other agent to
29 be administered to persons who have been infected with human
30 immunodeficiency virus to counteract the effects of that infection.

31 (iii) Any drug or biologic used to treat opportunistic infections
32 associated with acquired immune deficiency syndrome, that have
33 been found to be medically accepted indications and that has either
34 been approved by the federal Food and Drug Administration or
35 recognized for that use in one of the following:

36 (I) The American Medical Association Drug Evaluations.

37 (II) The United States Pharmacopoeia Dispensing Information
38 *or any other similar drug compendium, as determined annually*
39 *by the State Department of Health Care Services on the basis of*
40 *factors, including, but not limited to, the breadth of listings, use*

1 *of prespecified published criteria for weighing evidence, and*
2 *inclusion on a list of compendia approved by the federal Centers*
3 *for Medicare and Medicaid Services.*

4 (III) Two articles from peer reviewed medical journals that
5 present data supporting the proposed use or uses as generally safe
6 and effective.

7 (iv) Any drug or biologic used to treat the chemotherapy-induced
8 suppression of the human immune system resulting from the
9 treatment of acquired immune deficiency syndrome.

10 (3) The department shall add any drug deemed to be approved
11 pursuant to paragraph (1) to the Medi-Cal list of contract drugs or
12 allow the provision of the drug as a Medi-Cal benefit, subject to
13 utilization controls, pursuant to paragraph (2), only if the
14 manufacturer of the drug has executed a contract with the Centers
15 for Medicare and Medicaid Services which provides for rebates
16 in accordance with Section 1396r-8 of Title 42 of the United States
17 Code.

18 (b) Any drug deemed to be approved pursuant to paragraph (1)
19 of subdivision (a) shall be immediately added to the Medi-Cal list
20 of contract drugs, and shall be exempt from the contract
21 requirements of Section 14105.33.

22 (c) If it is determined pursuant to subdivision (c) of Section
23 14105.39 that a drug to which subdivision (a) applies should not
24 be placed on the Medi-Cal list of contract drugs, that drug shall
25 no longer be deemed to be approved for addition to the list of
26 contract drugs pursuant to subdivision (a).

27 SEC. 16. Section 14133.2 of the Welfare and Institutions Code
28 is amended to read:

29 14133.2. (a) The director shall include in the Medi-Cal list of
30 contract drugs any drug approved for the treatment of cancer by
31 the federal Food and Drug Administration, so long as the
32 manufacturer has executed a contract with the Health Care
33 Financing Administration which provides for rebates in accordance
34 with Section 1396r-8 of Title 42 of the United States Code. These
35 drugs shall be exempt from the contract requirements of Section
36 14105.33.

37 (b) In addition to any drug added to the list of contract drugs
38 pursuant to subdivision (a), any drug that meets either of the
39 following criteria and for which the manufacturer has executed a
40 contract with the Health Care Financing Administration that

1 provides for rebates in accordance with Section 1396r-8 of Title
2 42 of the United States Code, shall be a Medi-Cal benefit, subject
3 to utilization controls, unless the contract requirements of Section
4 14105.33 have been complied with:

5 (1) Any drug approved by the federal Food and Drug
6 Administration for treatment of opportunistic infections associated
7 with cancer.

8 (2) Any drug or biologic used in an anticancer chemotherapeutic
9 regimen for a medically accepted indication, which has either been
10 approved by the federal Food and Drug Administration, or
11 recognized for that use in one of the following:

12 (A) The American Medical Association Drug Evaluations.

13 (B) The United States Pharmacopoeia Dispensing Information
14 *or any other similar drug compendium, as determined annually*
15 *by the State Department of Health Care Services on the basis of*
16 *factors, including, but not limited to, the breadth of listings, use*
17 *of prespecified published criteria for weighing evidence, and*
18 *inclusion on a list of compendia approved by the federal Centers*
19 *for Medicare and Medicaid Services.*

20 (C) Two articles from peer reviewed medical journals that
21 present data supporting the proposed use or uses as generally safe
22 and effective.